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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,139	03/23/2006	Jonathan Marc Cohen	36119.232US/AM101272US	1771

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EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,139	COHEN ET AL.	
	Examiner	Art Unit	
	JODY L. KAROL	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/22/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 38-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 38-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/15/2006 and 2/1/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/US04/10698 International Filing Date: 4/7/2004, which claims priority to Application No. 60/462,808. Claims 1-6 and 38-75 are pending and examined on the merits herein.

Information Disclosure Statement

1. The information disclosure statements (IDS) filed on 2/1/2007 and 2/15/2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered.

Priority

2. Acknowledgment is made of applicant's claim for domestic priority based on the US Provisional Application No. 60/608,926 filed on 8/11/2003.

However, the disclosure of the provisional application fails to provide adequate support in the manner provided by the first paragraph of 35 U.S.C. 112 for the instant claims. In particular, the provisional application does no provide support for the aminocarboxylic chelating agents EGTA and CyDTA. The provisional application only discloses EDTA, DTPA, HEDTA, or NTA as suitable chelating agents. Accordingly the instant claims do not receive benefit of the provisional application.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6 and 38-75 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-90 of U.S. Patent No. 6,900,184 B2 in view of Schlesinger et al. (US 5,763,480).

The instant claims are directed to pharmaceutical compositions comprising piperacillin, tazobactam, and an aminocarboxylic chelating agent or salts thereof, a process for the manufacture of a reconstitutable form of said composition, and a method of treatment or control of bacterial infections caused by piperacillin/tazobactam susceptible bacteria comprising administering said composition parenterally.

The patented claims teach compositions comprising piperacillin in 8 to 500 mg/mL, tazobactam in 0.1 to 125 mg/mL, and an aminocarboxylic acid chelating agent in 0.002 to 10 mg/mL or 0.003 to 1mg/mL, wherein the composition further comprises a buffer such as a sodium citrate buffer in 0.25 to 25 mg/mL, and wherein the buffer is adapted to maintain the pH within the range of 6.5-7.5, or substantially 6.5 as claimed in the instant claims 1-4, 6, 48-52, and 57-58 (see column 15, claims 1-2, 7-8, 17-18, 21-23, and column 16, claims 30-31). The patented claims further teach a composition comprising the sodium salt of piperacillin, tazobactam, and pharmaceutically acceptable salts (i.e. sodium) of the chelating agent as claimed in the instant claim 5 (see column 15, claims 3-5, and column 3, lines 48-51). The patented claims further teach compositions further comprising an aminoglycoside such as amikacin or tobramycin in 0.1 to 75 mg/mL, or dextrose in 5 to 100 mg/mL as claimed in the instant claims 38-41, 53-56 (see column 15, claims 9-16, and column 16, claims 24-29). The patented claims also teach compositions in the form of a powder that can be reconstituted, frozen compositions, compositions ready for parenteral administration, compositions in a dose concentrate in a sealed contained, and compositions in the form of a solution and unite dose contained in an IV bag or IV bottle as claimed in the instant claims 41-47, and 59-

61 (see column 16, claims 32-43, column 17, claims 44-45, and column 19-20, claims 82-90). The patented claims also teach methods for the manufacture of a reconstitutable form of said pharmaceutical compositions in the form of a powder as claimed in the instant claims 62-69 (see columns 18-20, claims 63-90) and methods for the treatment or control of bacterial infections caused by piperacillin/tazobactam susceptible bacteria comprising administering said composition parenterally as claimed in the instant claims 70-75 (see columns 17-18, claims 53-62). The remaining patented claims teach formulations not specifically claimed in the instant application.

The patented claims do not teach EGTA or CyDTA as the aminocarboxylic chelating agents. However, the patented claims do teach that EDTA, DTPA, HEDTA, and NTA are acceptable aminocarboxylic chelating agents to be used in the compositions (see column 15, claim 5).

Schelsinger et al. teaches chelating agents used in parenteral compositions such as EDTA, EGTA, CDTA (i.e. CyDTA), or DPTA (see column 6, lines 40-41, column 8, lines 6-11, and column 12, lines 4-18).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, to employ an EGTA or a CyDTA chelating agent in the compositions and methods taught by the patented claims in place of EDTA, etc. One of ordinary kill in the art would have been motivated to do so because, absence a showing of unexpected results, EDTA, EGTA, and CyDTA are art-recognized equivalent chelating agents suitable for use in parenteral compositions.

6. Claims 1-6, 38-41, 48-58, and 70-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11250716 in view of Schlesinger et al. (US 5,763,480).

While the instant claims and the copending claims are not identical, they are both directed to compositions comprising piperacillin, tazobactam, an aminocarboxylic acid, and a buffer, and methods of treating a bacterial infection comprising administering said composition

The copending claims do not EGTA or CyDTA as the aminocarboxylic acid. However, the copending claims do teach EDTA (see claim 9 for example). Schelsinger et al. teaches chelating agents used in parenteral compositions such as EDTA, EGTA, CDTA (i.e. CyDTA), or DPTA (see column 6, lines 40-41, column 8, lines 6-11, and column 12, lines 4-18).

Schelsinger et al. teaches chelating agents used in parenteral compositions such as EDTA, EGTA, CDTA (i.e. CyDTA), or DPTA (see column 6, lines 40-41, column 8, lines 6-11, and column 12, lines 4-18).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, to employ an EGTA or a CyDTA chelating agent in the compositions and methods taught in the copending claims in place of EDTA, etc. One of ordinary kill in the art would have been motivated to do so because, absence a showing of unexpected results, EDTA, EGTA, and CyDTA are art-recognized equivalent chelating agents suitable for use in parenteral compositions.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-41, 55-56, 63-66, and 72-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the disclosure does not reasonably provide enablement for compositions comprising a combination of piperacillin and an aminoglycoside.

The claims are so broad that they encompass every member of the aminoglycoside antibiotics in a combination with piperacillin. However, it is well known in the art that aminoglycosides are incompatible with piperacillin. For example, the Zosyn® package insert (Reference CJ in IDS filed 2/15/2006), revised in March of 1999, teaches that penicillin-class drugs, such as piperacillin, inactivate aminoglycosides when they are mixed together. The reference further teaches that piperacillin likely forms a complex with the aminoglycoside, that the complexes are microbiologically inactive, and that the complexes possess unknown toxicity (see page 3, column 4, Drug Interactions). The instant specification gives no disclosure as to the incompatibility between piperacillin and aminoglycosides when they are mixed or combined together in

a same container. There is no working example showing biological activity of aminoglycoside being maintained when it is mixed with piperacillin. The instant specification also fails to provide sufficient guidance on how to prevent the interaction between the drugs when they are mixed together. Thus, it would require undue experimentation for one of skill in the art to address and solve the incompatibility problem between piperacillin and aminoglycosides. Accordingly, the instant claims are not enabled for composition comprising the combination of aminoglycosides and piperacillin.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JODY L. KAROL whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

/San-ming Hui/
Primary Examiner, Art Unit 1617